10/625437

Cofe

PATENT
127005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent No.: 7,031,426

Issued: April 18, 2006

Inventor(s): Iatrou et al.

Assignee: GE Medical Systems Global Technology Company, LLC

For: METHODS AND SYSTEM FOR DETECTING COMPONENTS OF PLAQUE

CERTIFICATE OF MAILING

I certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on April 11, 2008.

Eric T. Krischke
Reg. No. 42,769

Attention Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REQUEST FOR CERTIFICATE OF CORRECTION OF PATENT UNDER 37 C.F.R. 1.322(a)

Sir:

Attached is Form PTO/SB/44 suitable for printing.

Submitted herewith is a copy of the Notice of Allowance and Fee(s) Due and the Notice of Allowability dated November 10, 2005 including an Examiner's Amendment amending Claim 15, and a copy of the Amendment filed September 13, 2005. Applicants respectfully submit that the corrections shown below are in accordance with the Examiners Amendment dated November 10, 2005 and the Amendment filed September 13, 2005. The corrections thereof do not involve such changes in the patent as would constitute new matter or would require re-examination. Applicants respectfully request a Certificate of Correction for the following:

In Title, delete "SYSTEM" and insert therefor --SYSTEMS--.

In Claim 14, column 12, line 24, delete "plaque; and" and insert therefor --plaque;--.

In Claim 14, column 12, line 25, after "phantom;" insert --and--.

In Claim 20, column 13, line 10, delete "administer a the " and insert therefor --administer the--.

The corrections are not due to any error by Applicants and no fee is due.

The Assignment for this patent is recorded on Reel 014329/Frame 0153.

Respectfully submitted,

Date: April 11, 2008

Eric T. Krischke

Eric T. Krischke
Reg. No. 42,769
ARMSTRONG TEASDALE LLP
One Metropolitan Square, Suite 2600
St. Louis, Missouri 63102-2740
(314) 621-5070

PTO/SB/44 (09-07)
Approved for use through 08/31/2010. OMB 0651-0033
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 7,031,426
APPLICATION NO. : 10/625,437
ISSUE DATE : April 18, 2006
INVENTOR(S) : Iatrou et al.

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Title, delete "SYSTEM" and insert therefor --SYSTEMS--.
In Claim 14, column 12, line 24, delete "plaque; and" and insert therefor --plaque;--.
In Claim 14, column 12, line 25, after "phantom;" insert --and--.
In Claim 20, column 13, line 10, delete "administer a the " and insert therefor --administer the--.

MAILING ADDRESS OF SENDER:
Eric T. Krischke
Armstrong Teasdale LLP
One Metropolitan Sq., Suite 2600
St. Louis, MO 63102

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

7590 11/10/2005

Patrick W. Rasche
Armstrong Teasdale LLP
Suite 2600
One Metropolitan Square
Saint Louis, MO 63102-2740

EXAMINER
KAO, CHIH CHENG G

ART UNIT	PAPER NUMBER
2882	

DATE MAILED: 11/10/2005

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,437	07/23/2003	Maria Iatrou	127005	7917

TITLE OF INVENTION: METHODS AND SYSTEMS FOR DETECTING COMPONENTS OF PLAQUE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1400	$300	$1700	02/10/2006

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

COPY

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,437	07/23/2003	Maria Iatrou	127005	7917

7590 11/10/2005

Patrick W. Rasche
Armstrong Teasdale LLP
Suite 2600
One Metropolitan Square
Saint Louis, MO 63102-2740

EXAMINER	
KAO, CHIH CHENG G	
ART UNIT	**PAPER NUMBER**
2882	

DATE MAILED: 11/10/2005

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 51 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 51 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571) 272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

COPY

AK

Notice of Allowability	Application No. 10/625,437	Applicant(s) IATROU ET AL.	
	Examiner Chih-Cheng Glen Kao	Art Unit 2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *10/13/05*.

2. ☒ The allowed claim(s) is/are *1-9,11-21 and 23-27*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 10/13/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with William Zychlewicz on 10/24/05.

2. The application has been amended as follows:

In claim 15, line 8, insert - -and- - after "phantom;".

Reasons for Allowance

3. Claims 1-9, 11-21, and 23-27 are allowed. The following is an examiner's statement of reasons for allowance.

4. Regarding claim 1, prior art fails to disclose or fairly suggest a method including quantifying components of plaque by determining a weight sum of densities of pixels of an image of an organ including the plaque, in combination with all the limitations in the claim. Claims 2-9 and 11-13 are allowed by virtue of their dependency.

5. Regarding claim 14, prior art fails to disclose or fairly suggest a method including enabling visualization of restenosis within one of a metal stent and a metal valve by repeating

obtaining components of plaque after scanning a patient having the one of the metal stent and the metal valve, in combination with all the limitations in the claim.

6. Regarding claim 15, prior art fails to disclose or fairly suggest a system including a computer configured to repeat detection of components of plaque after instructing a user to administer a temperature-sensitive contrast agent to accentuate a visualization of the plaque, in combination with all the limitations in the claim. Claims 16-21 and 23-25 are allowed by virtue of their dependency.

7. Regarding claim 26, prior art fails to disclose or fairly suggest a computer readable medium encoded with a program configured to instruct a computer to repeat detection of components of plaque after instructing a user to administer a contrast agent to accentuate a visualization of the plaque, in combination with all the limitations in the claim.

8. Regarding claim 27, prior art fails to disclose or fairly suggest a computer encoded with a program configured to quantify components of plaque by determining a weight sum of densities, greater than a specific amount, of pixels of an image of an organ including the plaque, in combination with all the limitations in the claim.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Cheng Glen Kao whose telephone number is (571) 272-2492. The examiner can normally be reached on M - F (9 am to 5 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gk

EDWARD J. GLICK
SUPERVISORY PATENT EXAMINER

COPY

Express Mail Label No. EV 679278094 US

PTO/SB/08A (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	10/625,437
Filing Date	July 23, 2003
First Named Inventor	Maria Introu
Art Unit	2882
Examiner Name	Kao, Chih Cheng G.
Attorney Docket Number	127005

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- ~~6,290,902 B1~~	05-15-2001	Hu et al.	
		US- 5,867,553	02-02-1999	Gordon et al.	
		US- 5,335,260	08-02-1994	Arnold	
		US-			
		US- 6,233,304 B1			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
	FA	WO 0033252 A	06-08-2000	General Electric Co.		
	FB	WO 94 12855 A	06-09-1994	Arnold, Ben A.		

Examiner Signature		Date Considered	10/21/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3]Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5]Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6]Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

COPY

10/13/05

PTO/SB/08B (07-05)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	10/625,437
Filing Date	July 23, 2003
First Named Inventor	Maria Introu
Art Unit	2882
Examiner Name	Kao, Chih Cheng G.
Attorney Docket Number	127005

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
CK	8A	International Search Report, International Application No. ~~PCT/US03/22861~~ PCT/US03/22861, Classification of Subject Matter: IPC 7, A61B6/03, Search completion date: 10-15-03, 4 pages	

Examiner Signature		Date Considered	10/21/05

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

COPY

THE UNITED STATES PATENT OFFICE IS REQUESTED TO IMPRESS ITS STAMP ON THIS CARD AND PLACE SAME IN THE OUTGOING MAIL TO SHOW THE FOLLOWING PAPERS HAVE BEEN RECEIVED.

Atty Dkt. No.: 127005 (12553-320)
Inventors: Iatrou et al.
Serial No.: 10/625,437
Filed: July 23, 2003
For: METHODS AND SYSTEMS FOR DETECTING COMPONENTS OF PLAQUE

Enclosed:

Amendment (39 pgs.), in response to Office Action dated 7/13/05 and made final
Transmittal Form (3 pgs.), in duplicate

WJZ/NP/ls
Mailed: September 13, 2005
Express Mail Label No. EV504792811US

EV504792811US

Entered into PAGE/PIPS
Date 10-05-05
By: E. Deaton

SCANNED
By: 9/28/05

Express Mail Label No. : 504792811US

COPY

PATENT
127005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Iatrou et al.	:	
	:	Art Unit: 2882
Serial No.: 10/625,437	:	
	:	Examiner: Kao, Chih Cheng G.
Filed: July 23, 2003	:	
	:	
For: METHODS AND SYSTEMS FOR DETECTING COMPONENTS OF PLAQUE	:	

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

1. Transmitted herewith is:
   Amendment (39 pgs.), in response to Office Action dated July 13, 2005 and made final
   Transmittal Form (3 pgs.), in duplicate
   Return Post Card

STATUS

2. Applicant
   ☐ claims small entity status.
   ☒ is other than a small entity.

CERTIFICATE OF MAILING BY EXPRESS MAIL TO
THE COMMISSIONER FOR PATENTS

Express Mail No. EV504792811US
Date: September 13, 2005

I hereby certify that the documents listed above are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above in an envelope addressed to Mail Stop: AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

William J. Zychlewicz, Reg. No. 51,366

EXTENSION OF TERM

3. The proceedings herein are for a patent application and the provisions of 37 C.F.R. 1.136 apply.

(complete (a) or (b), as applicable)

(a) ____ Applicant petitions for an extension of time under 37 C.F.R. 1.136
(Fees: 37 C.F.R. 1.17(a)-(d) for the total number of months checked below:)

Extension for response within:	Other than small entity Fee	Small entity Fee (if applicable)
____ first month	$ 120.00	$ 60.00
____ second month	$ 450.00	$ 225.00
____ third month	$ 1,020.00	$ 510.00
____ fourth month	$1,590.00	$ 795.00
____ fifth month	$2,160.00	$1,080.00

Fee: $ _____

If an additional extension of time is required, please consider this a petition therefor.

(Check and complete the next item, if applicable)

____ An extension of _____ months has already been secured. The fee paid therefor $_____ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request $_____

OR

(b) X ____ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition for extension of time.

COPY

FEE FOR CLAIMS

4. The fee for claims (37 C.F.R. 1.16(b)-(d)) has been calculated as shown below:

	(Col. 1) CLAIMS REMAINING AFTER AMENDMENT		(Col. 2) HIGHEST NO. PREVIOUSLY PAID FOR	(Col. 3) PRESENT EXTRA	SMALL ENTITY ADDITIONAL. RATE FEE	OR	OTHER THAN SMALL ENTITY ADDITIONAL RATE FEE
TOTAL INDEP.		MINUS		=	x $25.00 = $		x $50.00 = $
		MINUS		=	x $100.00 = $		x $200.00 = $
___ FIRST PRESENTATION OF MULTIPLE DEP. CLAIM					+ $180.00 = $		+ $360.00 = $
					TOTAL ADDITIONAL FEE $	OR	TOTAL ADDITIONAL FEE $

(a) ☒ No additional fee for Claims is required

OR

(b) ☐ Total additional fee for claims required $ _____

FEE PAYMENT

5. Attached is a check in the sum of $_____

☐ Charge Deposit Account No. 01-2384 the sum of $_____.
A duplicate of this transmittal is attached.

FEE DEFICIENCY

6. ☒ If any additional extension and/or fee is required, charge Deposit Account No. 01-2384.

AND/OR

☒ If any additional fee for claims is required, charge Deposit Account No. 01-2384.

7. ☐ Other:

William J. Zychlewicz
Reg. No. 51,366
ARMSTRONG TEASDALE LLP
One Metropolitan Square, Suite 2600
St. Louis, MO 63102
314-621-5070

Express Mail Label No. EV504792811US

PATENT
Atty. Dkt. No.: 127005

COPY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Iatrou et al.

Serial No.: 10/625,437

Filed: July 23, 2003

For: METHODS AND SYSTEMS FOR DETECTING COMPONENTS OF PLAQUE

Art Unit: 2882

Examiner: Kao, Chih Cheng G.

AMENDMENT

Mail Stop: AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In response to the Office Action dated July 13, 2005, and made final, Applicants respectfully request consideration and entry of the following amendment.

IN THE CLAIMS

1. (currently amended) A method comprising:

detecting components of plaque using a multi-energy computed tomography (MECT) system, wherein said detecting the components of the plaque includes generating a look-up table by using at least one ~~phantom.~~phantom; and

quantifying the components of the plaque by determining a weighted sum of densities of pixels of an image of an organ including the plaque.

2. (previously presented) A method in accordance with Claim 1 wherein the phantom includes a simulated phantom, said method comprising:

obtaining the components of the plaque by using the generated look-up table, wherein said generating the look-up table includes producing the look-up table by using the simulated phantom, wherein the look-up table maps different densities of a selected basis material of the simulated phantom to projection data for different energy spectra.

3. (previously presented) A method in accordance with Claim 2 wherein said generating the look-up table comprises:

obtaining first and second sets of projection data of the simulated phantom with a set of known material properties by:

placing the simulated phantom in a scanning field of the MECT system; and

scanning the simulated phantom at first and second energy spectra using the MECT system.

4. (previously presented) A method in accordance with Claim 3 wherein said obtaining the components of the plaque comprises:

placing an object in the scanning field of the MECT system;

scanning the object at the first and second energy spectra using the MECT system to obtain projection data of the object; and

enabling, utilizing the look-up table, a reconstruction of images of a distribution of densities of the object by reversely mapping the projection data of the object to densities of the selected basis material, wherein the selected basis material includes at least one of iodine and water.

5. (previously presented) A method in accordance with Claim 1 wherein said generating the look-up table comprises:

obtaining projection data of the phantom with a set of known material properties by:

placing the phantom in a scanning field of the MECT system;

scanning the phantom using the MECT system;

counting photons generated from the scan; and

distinguishing the photons based on an energy threshold.

6. (previously presented) A method in accordance with Claim 5 wherein said obtaining the components of the plaque comprises:

placing an object in the scanning field of the MECT system;

scanning the object using the MECT system to obtain projection data of the object; and

enabling, utilizing the look-up table, a reconstruction of images of a distribution of densities of the object by reversely mapping the projection data of the object to densities of the selected basis material, wherein the selected basis material includes at least one of iodine and water.

7. (previously presented) A method in accordance with Claim 1 further comprising:

performing additional scans of an object at different times; and

repeating said detecting the components of the plaque.

8. (original) A method in accordance with Claim 1 further comprising:

administering a contrast agent in at least one of lipid-avid agents, plaque specific antigens, and plaque cells; and

repeating said detecting the components of the plaque.

9. (original) A method in accordance with Claim 1 further comprising:

administering a temperature-sensitive contrast agent in an inflamed plaque; and

repeating said detecting the components of the plaque.

10. (canceled)

11. (currently amended) A method in accordance with ~~Claim 10~~Claim 1 wherein said quantifying the components of the plaque comprises:

calculating composition distributions of the plaque; and

calculating total plaque burden.

12. (previously presented) A method in accordance with Claim 1 further comprising:

displaying at least one of a 2-dimensional (2D) and a 3-dimensional (3D) image of the components of the plaque on a wall of an organ of an object; and

viewing, from a viewpoint, a volume of the plaque in the 3D image.

13. (original) A method in accordance with Claim 1 further comprising:

improving quality of images of an object having at least one of metal stents and valves by removing beam-hardening artifacts in the images; and

enabling visualization of restenosis within at least one of the metal stents by repeating said detecting the components of plaque.

14. (currently amended) A method for detecting components of plaque comprising:

generating information regarding projection data of phantoms by using a multi-energy computed tomography (MECT) system;

generating a look-up table by using one of the ~~phantoms; and~~phantoms;

obtaining the components of the plaque from the ~~information.~~information; and

enabling visualization of restenosis within one of a metal stent and a metal valve by repeating said obtaining the components of plaque after scanning a patient having the one of the metal stent and the metal valve.

15. (currently amended) A multi-energy computed tomography (MECT) system comprising:

at least one radiation source configured to transmit x-rays that intersect an object;

at least one detector configured to detect the x-rays;

a controller coupled to the detector; and

a computer configured to:

instruct the MECT system to detect components of ~~plaque; and~~plaque;

generate a look-up table by using at least one ~~phantom.~~phantom;

repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent to accentuate a visualization of the plaque.

16. (previously presented) An MECT system in accordance with Claim 15, wherein the at least one phantom includes a simulated phantom, and to detect the components of the plaque, said computer is configured to:

produce the look-up table by using the simulated phantom, wherein the look-up table maps different densities of a selected basis material of the phantom to projection data for different energy spectra; and

obtain the components of the plaque by using the look-up table.

17. (previously presented) An MECT system in accordance with Claim 16, wherein to generate the look-up table, said computer is configured to:

obtain first and second sets of density distribution images of the simulated phantom with a set of known material properties by:

simulating placement of the simulated phantom in a scanning field of the MECT system; and

simulating a scan of the simulated phantom at first and second energy levels using the MECT system.

18. (previously presented) An MECT system in accordance with Claim 17, wherein to obtain the components of the plaque, said computer is configured to:

instruct the MECT system to place an object in the scanning field of the MECT system;

instruct the MECT system to scan the object at the first and second energy levels to obtain projection data of the object; and

determine, from the look-up table, densities of the object by reversely mapping the projection data of the object to the densities of the selected basis material, wherein the selected basis material includes at least one of iodine and water.

19. (original) An MECT system in accordance with Claim 15 wherein said computer is configured to:

instruct the MECT system to perform additional scans of the object at different times; and

repeat the detection of the components of the plaque.

20. (original) An MECT system in accordance with Claim 15 wherein said computer is configured to:

instruct a user to administer a contrast agent in at least one of lipid-avid agents of the plaque, plaque specific antigens of the plaque, and plaque cells of the plaque; and

repeat the detection of the components of the plaque.

21. (currently amended) An MECT system in accordance with Claim 15 wherein said computer is ~~configured to:~~configured to instruct ~~a user~~the user to administer ~~a temperature-sensitive~~the temperature-sensitive contrast agent in an inflamed plaque~~; and~~

~~repeat the detection of the components of the plaque~~.

22. (canceled)

23. (currently amended) An MECT system in accordance with ~~Claim 22~~Claim 15, wherein to quantify the components of the plaque, said computer is configured to:

calculate composition distributions of the plaque; and

calculate total plaque burden.

24. (original) An MECT system in accordance with Claim 15 wherein said computer is configured to:

instruct a display device to display at least one of a 2-dimensional (2D) and a 3-dimensional (3D) image of the components of the plaque on a wall of an organ of the object; and

enable viewing, from a viewpoint, a volume of the plaque in the 3D image.

25. (previously presented) An MECT system in accordance with Claim 15, wherein said computer is configured to:

improve quality of images of an object having at least one of metal stents and valves by removing beam-hardening artifacts in the images; and

enable visualization of restenosis within at least one of the metal stents by repeating said detecting the components of plaque.

26. (currently amended) A computer readable medium encoded with a program configured to instruct a computer to detect components of plaque within an object that is scanned using a multi-energy tomography (MECT) system, the program further configured to instruct the computer to generate, by using at least one phantom, a look-up table that maps different densities of a selected basis material of the phantom to projection data for different energy spectra, and to repeat the detection of the components of the plaque after instructing a user to administer a contrast agent to accentuate a visualization of the plaque.

27. (currently amended) A computer encoded with a program configured to instruct an MECT system to detect components of plaque within an object that is scanned using the MECT system, the program further configured to instruct the computer to generate, by using at least one phantom, a look-up table that maps different densities of a selected basis material of the phantom to projection data for different energy spectra, and to quantify the components of the plaque by determining a weighted sum of densities, greater than a specific amount, of pixels of an image of an organ including the plaque.

REMARKS

The Office Action mailed July 13, 2005 has been carefully reviewed and the foregoing amendment has been made in consequence thereof.

Claims 1-9, 11-21, and 23-27 are pending in this application. Claims 1-27 stand rejected. Claims 1, 11, 14, 15, 21, 23, 26, and 27 have been amended. No new matter has been added.

Applicants respectfully submit that a copy, with Examiner's initials and signature, of the supplemental information disclosure statement (PTO/SB/08A) filed on December 3, 2003 has not been provided with the Office Action. Applicants respectfully request that an executed copy of the information disclosure statement be provided.

The rejection of Claim 1 under 35 U.S.C. § 103(a) as being unpatentable over Arfelli ("Synchrotron light and imaging systems for medical radiology") in view of Urchuk et al. (U.S. Patent 6,148,057) is respectfully traversed.

Claim 1 recites a method comprising "detecting components of plaque using a multi-energy computed tomography (MECT) system, wherein said detecting the components of the plaque includes generating a look-up table by using at least one phantom; and quantifying the components of the plaque by determining a weighted sum of densities of pixels of an image of an organ including the plaque."

Arfelli describes a method including multiple energy computed tomography (MECT). MECT was first developed at a medical facility with a program for imaging human neck and head with single- and dual-energy methods (page 15, column 2). In the method, dual-photon imaging will be applied in the study of tissue characterization as carotid artery atherosclerotic plaque composition (page 15, column 2).

Urchuk et al. describe a method including generating nonlinear calibration tables using a two-step process (column 6, lines 39-40). First, a set of detector-dependent gain errors is estimated by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom, which is formed from

multiple plastic slabs (column 6, lines 40-45). Next, the error estimates are used to generate an array of polynomial-based look-up tables, one for each X-ray detector (column 6, lines 45-47).

Neither Arfelli nor Urchuk et al., considered alone or in combination, describe or suggest a method as recited in Claim 1. Specifically, neither Arfelli nor Urchuk et al., considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities of pixels of an image of an organ including the plaque. Rather, Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Accordingly, neither Arfelli nor Urchuk et al., considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities as recited in Claim 1. For the reasons set forth above, Claim 1 is submitted to be patentable over Arfelli and further in view of Urchuk et al.

For at least the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 1 be withdrawn.

The rejection of Claim 5 and 6 under 35 U.S.C. § 103(a) as being unpatentable over Arfelli and Urchuk et al., and further in view of Vinegar et al. (U.S. Patent 4,571,491) and Tsutsui et al. (U.S. Patent 5,396,530) is respectfully traversed.

Arfelli and Urchuk et al. are described above.

Vinegar et al. describe a method of obtaining an atomic number image of an unknown material (abstract). A plurality of calibration materials which have a plurality of different known atomic numbers and densities are scanned with a computerized axial tomographic scanner (CAT) at first and second energies to determine attenuation coefficients for the plurality of calibration materials at these energies (abstract). Energy-dependent coefficients at the first and second energies are determined from the attenuation coefficients for the plurality of calibration materials at the first and second energies according to a predetermined

relation (abstract). An unknown material is scanned with the CAT at the first and second energies to determine the attenuation coefficients at a plurality of points in a cross section of the unknown material at these energies (abstract). The determined energy-dependent coefficients and the determined attenuation coefficients for the unknown material at the first and second energies are used to determine an atomic number image for the unknown material (abstract).

Tsutsui et al. describe an X-ray source that applies an application voltage of 100 kV to an X-ray tube of a constant voltage of 3 mV to generate an X-ray beam, and the X-ray energy spectrum is divided into two energy bands beforehand by using materials having an energy absorbing end at about 50 KeV denominated a K-edge filter (column 5, lines 16-24). An object is irradiated by the divided X-ray energy bands (column 5, lines 25-26). X-ray photons transmitted through the object are separated into two energy bands by using two discriminator comparators and a pulse counting measurement is conducted by using a one-dimensional semiconductor radiation detector (column 5, lines 27-34).

Claims 5 and 6 depend indirectly from independent Claim 1. None of Arfelli, Urchuk et al., Vinegar et al., and Tsutsui et al., considered alone or in combination, describe or suggest a method as recited in Claim 1. Specifically, none of Arfelli, Urchuk et al., Vinegar et al., and Tsutsui et al., considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities of pixels of an image of an organ including the plaque. Rather, Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Vinegar et al. describe scanning a plurality of calibration materials which have a plurality of different known atomic numbers and densities with a computerized axial tomographic scanner (CAT) at first and second energies to determine attenuation coefficients for the plurality of calibration materials at the energies. Vinegar et al. further describe determining energy-dependent coefficients at the first and second energies from the attenuation coefficients for the plurality of calibration materials at the first and second energies. Vinegar et al. also describe scanning an unknown material with the CAT at the first

and second energies to determine the attenuation coefficients at a plurality of points in a cross section of the unknown material at the energies. Vinegar et al. describe using the determined energy-dependent coefficients and the determined attenuation coefficients for the unknown material at the first and second energies to determine an atomic number image for the unknown material. Tsutsui et al. describe separating X-ray photons transmitted through an object into two energy bands by using two discriminator comparators and conducting a pulse counting measurement by using a one-dimensional semiconductor radiation detector. Accordingly, none of Arfelli, Urchuk et al., Vinegar et al., and Tsutsui et al., considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities as recited in Claim 1. For the reasons set forth above, Claim 1 is submitted to be patentable over Arfelli and Urchuk et al., and further in view of Vinegar et al. and Tsutsui et al.

When the recitations of Claims 5 and 6 are considered in combination with the recitations of Claim 1, Applicants submit that dependent Claims 5 and 6 likewise are patentable over Arfelli and Urchuk et al., and further in view of Vinegar et al. and Tsutsui et al.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claims 5-6 over Arfelli and Urchuk et al., and further in view of Vinegar et al. and Tsutsui et al. be withdrawn.

The rejection of Claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Arfelli and Urchuk et al., and further in view of Walters (U.S. Patent 5,115,394) is respectfully traversed.

Arfelli and Urchuk et al. are described above.

Walters describes dual energy scanning systems and methods that are a solution to many problems where two scans are made at a combined dose equal to a dose that would have been used if a single energy scan approach had been used (column 1, lines 55-59). By taking two sets of measurements, one at a high KVP (kilovolts peak) at a specified dose level and another at a low KVP and at a specified corresponding dose level, information may be obtained from which estimates may be made about distribution functions of attenuation coefficients at a given reconstruction energy (column 1, lines 59-65).

Claim 7 depends directly from independent Claim 1. None of Arfelli, Urchuk et al., and Walters, considered alone or in combination, describe or suggest a method as recited in Claim 1. Specifically, none of Arfelli, Urchuk et al., and Walters, considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities of pixels of an image of an organ including the plaque. Rather, Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Walters describes taking two sets of measurements, one at a high kilovolts peak (KVP) at a specified dose level, and another at a low KVP and at a specified corresponding dose level. Accordingly, none of Arfelli, Urchuk et al., and Walters, considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities as recited in Claim 1. For the reasons set forth above, Claim 1 is submitted to be patentable over Arfelli and Urchuk et al., and further in view of Walters.

When the recitations of Claim 7 are considered in combination with the recitations of Claim 1, Applicants submit that dependent Claim 7 likewise is patentable over Arfelli and Urchuk et al., and further in view of Walters.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 7 over Arfelli and Urchuk et al., and further in view of Walters be withdrawn.

The rejection of Claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Arfelli and Urchuk et al., and further in view of Teirstein et al. (U.S. Patent Application 2001/0018042) and Walters is respectfully traversed.

Arfelli, Urchuk et al., and Walters are described above.

Teirstein et al. describe in vivo methods for detection of vulnerable plaque in a subject in need thereof (abstract). In the methods, the subject is administered a diagnostic amount of a biologically compatible detectable lipid-avid agent, the detectable lipid-avid

agent is allowed to penetrate arterial walls and attach to any lipid accumulations of oxidized LDL-cholesterol in arterial walls in the wall of an artery, unbound detectable lipid-avid agent is allowed to clear from the subject by natural processes, and a presence of the detectable lipid-avid agent attached to the lipid accumulation in the wall of the artery is detected (abstract).

Claim 8 depends directly from independent Claim 1. None of Arfelli, Urchuk et al., Teirstein et al., and Walters, considered alone or in combination, describe or suggest a method as recited in Claim 1. Specifically, none of Arfelli, Urchuk et al., Teirstein et al., and Walters, considered alone or in combination, considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities of pixels of an image of an organ including the plaque. Rather, Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Teirstein et al. describe detecting a presence of detectable lipid-avid agent attached to a lipid accumulation in a wall of an artery. Walters describes taking two sets of measurements, one at a high kilovolts peak (KVP) at a specified dose level, and another at a low KVP and at a specified corresponding dose level. Accordingly, none of Arfelli, Urchuk et al., Teirstein et al., and Walters, considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities as recited in Claim 1. For the reasons set forth above, Claim 1 is submitted to be patentable over Arfelli and Urchuk et al., and further in view of Teirstein et al. and Walters

When the recitations of Claim 8 are considered in combination with the recitations of Claim 1, Applicants submit that dependent Claim 8 likewise is patentable over Arfelli and Urchuk et al., and further in view of Teirstein et al. and Walters.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 8 over Arfelli and Urchuk et al., and further in view of Teirstein et al. and Walters.

The rejection of Claim 9 under 35 U.S.C. § 103(a) as being unpatentable over Arfelli and Urchuk et al., and further in view of Falotico et al. (U.S. Patent Application 2003/0060877) and Walters is respectfully traversed.

Arfelli, Urchuk et al., and Walters are described above.

Falotico et al. describe new diagnostic technologies to identify a location of vulnerable plaques in a plurality of coronary arteries (paragraph 26). The new technologies include refined magnetic resonance imaging (MRI), thermal sensors that measure a temperature of an arterial wall on a premise that an inflammatory process generates heat, elasticity sensors, intravascular ultrasound, optical coherence tomography (OCT), contrast agents, and near-infrared and infrared light (paragraph 26).

Claim 9 depends directly from independent Claim 1. None of Arfelli, Urchuk et al., Falotico et al., and Walters, considered alone or in combination, describe or suggest a method as recited in Claim 1. Specifically, none of Arfelli, Urchuk et al., Falotico et al., and Walters, considered alone or in combination, considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities of pixels of an image of an organ including the plaque. Rather, Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Falotico et al. describe identifying a location of vulnerable plaques in a plurality of coronary arteries by using contrast agents. Walters describes taking two sets of measurements, one at a high kilovolts peak (KVP) at a specified dose level, and another at a low KVP and at a specified corresponding dose level. Accordingly, none of Arfelli, Urchuk et al., Falotico et al., and Walters, considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities as recited in Claim 1. For the reasons set forth above, Claim 1 is submitted to be patentable over Arfelli and Urchuk et al., and further in view of Falotico et al. and Walters.

When the recitations of Claim 9 are considered in combination with the recitations of Claim 1, Applicants submit that dependent Claim 9 likewise is patentable over Arfelli and Urchuk et al., and further in view of Falotico et al. and Walters.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 9 over Arfelli and Urchuk et al., and further in view of Falotico et al. and Walters.

The rejection of Claim 10 under 35 U.S.C. § 103(a) as being unpatentable over Arfelli and Urchuk et al., and further in view of Arnold (U.S. Patent 5,335,260) is respectfully traversed.

Arfelli and Urchuk et al. are described above.

Arnold describes a method that utilizes an improved calibration phantom formed of a material which simulates properties of human tissue and contains calcium in a stable configuration (column 2, lines 48-54). The method provides improved accuracy and precision in quantification of calcium, bone mass and bone density by using conventional X-ray equipment (column 2, lines 48-54).

Claim 10 has been canceled.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 10 over Arfelli and Urchuk et al., and further in view of Arnold be withdrawn.

The rejection of Claim 11 under 35 U.S.C. § 103(a) as being unpatentable over Arfelli, Urchuk et al. and Arnold, and further in view of Kaufman et al. (U.S. Patent Application Publication 2003/0095693) is respectfully traversed.

Arfelli, Urchuk et al., and Arnold are described above.

Kaufman et al. describe coronary artery calcium quantitation that is a major focus in the effort to assess risk for coronary heart disease, to monitor progression of plaque development, and to potentially assess therapies and interventions designed to reduce mortality from coronary heart disease (paragraph 4). Although a rupture of soft plaque and subsequent thrombus formation is a major precursor of acute coronary events, in most

individuals it is believed that coronary calcium burden is also a valid surrogate or indicator of total plaque burden, including soft plaque (paragraph 4).

Claim 11 depends indirectly from independent Claim 1. None of Arfelli, Urchuk et al., Arnold, and Kaufman et al., considered alone or in combination, describe or suggest a method as recited in Claim 1. Specifically, none of Arfelli, Urchuk et al., Arnold, and Kaufman et al., considered alone or in combination, considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities of pixels of an image of an organ including the plaque. Rather, Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Arnold describes utilizing an improved calibration phantom formed of a material which simulates properties of human tissue and contains calcium in a stable configuration. Kaufman et al. describe indicating total plaque burden by quantifying coronary calcium burden. Accordingly, none of Arfelli, Urchuk et al., Arnold, and Kaufman et al., considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities as recited in Claim 1. For the reasons set forth above, Claim 1 is submitted to be patentable over Arfelli, Urchuk et al. and Arnold, and further in view of Kaufman et al.

When the recitations of Claim 11 are considered in combination with the recitations of Claim 1, Applicants submit that dependent Claim 11 likewise is patentable over Arfelli, Urchuk et al. and Arnold, and further in view of Kaufman et al.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 11 over Arfelli, Urchuk et al. and Arnold, and further in view of Kaufman et al.

The rejection of Claim 12 under 35 U.S.C. § 103(a) as being unpatentable over Arfelli and Urchuk et al., and further in view of Charles, Jr. et al. (U.S. Patent 6,816,564) and Fox et al. (U.S. Patent 5,668,846) is respectfully traversed.

Arfelli and Urchuk et al. are described above.

Charles, Jr. et al. describe a method in which two attenuations HH and HL at each pixel are used with a pair of functions of attenuation to compute equivalent thicknesses of the calibration materials, e.g., aluminum and acrylic (column 15, line 66 – column 15, line 3). HH is the attenuation at a high x-ray photon energy and HL is the attenuation at a low x-ray photon energy (column 15, lines 4-5). A proportionality relationship is then used to compute a tissue density based on the equivalent thicknesses of the calibration materials (column 16, lines 3-5).

Fox et al. describe a method in which a three dimensional image may be nutated (column 7, lines 13-15). The image may be nutated with a nutation angle to display the three dimensional image from varying points of view (column 7, lines 13-15).

Claim 12 depends directly from independent Claim 1. None of Arfelli, Urchuk et al., Charles, Jr. et al., and Fox et al., considered alone or in combination, describe or suggest a method as recited in Claim 1. Specifically, none of Arfelli, Urchuk et al., Charles, Jr. et al., and Fox et al., considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities of pixels of an image of an organ including the plaque. Rather, Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Charles, Jr. et al. describe using a proportionality relationship to compute a tissue density based on equivalent thicknesses of a plurality of calibration materials. Fox et al. describe nutating a three-dimensional image with a nutation angle to display the three dimensional image from varying points of view. Accordingly, none of Arfelli, Urchuk et al., Charles, Jr. et al., and Fox et al., considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities as recited in Claim 1. For the reasons set forth above, Claim 1 is submitted to be patentable over Arfelli and Urchuk et al., and further in view of Charles, Jr. et al. and Fox et al.

When the recitations of Claim 12 are considered in combination with the recitations of Claim 1, Applicants submit that dependent Claim 12 likewise is patentable over Arfelli and Urchuk et al., and further in view of Charles, Jr. et al. and Fox et al.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 12 over Arfelli and Urchuk et al., and further in view of Charles, Jr. et al. and Fox et al.

The rejection of Claim 13 under 35 U.S.C. § 103(a) as being unpatentable over Arfelli and Urchuk et al., and further in view of Vaillant et al. (EP 1087339), Regulla et al. (U.S. Patent 6,001,054), Gayer et al. (U.S. Patent 6,094,467), and Walters is respectfully traversed.

Arfelli, Urchuk et al., and Walters are described above.

Vaillant et al. describe a method in which stents are placed in coronary arteries (paragraph 3). The method also includes reconstructing a three-dimensional image of an element of interest like, for example, a vascular stent inserted in an organ such as a vessel (paragraph 5).

Regulla et al. describe a method for differential energy application for local dose enhancement of ionizing radiation. The method includes implanting a metallic stent which has not been made radioactive, to maintain a lumen of a carotid artery open to allow adequate flow of blood therethrough (column 4, lines 30-36).

Gayer et al. describe a method for improving visual definition in a CT X-ray image having high attenuation objects such as metal prostheses and implants (abstract). The method provides for determining extents of the high attenuation objects and reducing artifacts that the high attenuation objects cause in the image without completely removing the high attenuation objects from the image (abstract).

Claim 13 depends directly from independent Claim 1. None of Arfelli, Urchuk et al., Vaillant et al., Regulla et al., Gayer et al., and Walters, considered alone or in combination, describe or suggest a method as recited in Claim 1. Specifically, none of Arfelli, Urchuk et al., Vaillant et al., Regulla et al., Gayer et al., and Walters, considered alone or in combination, considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities of pixels of an image

of an organ including the plaque. Rather, Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Vaillant et al. describe reconstructing a three-dimensional image of an element of interest like, for example, a vascular stent inserted in an organ such as a vessel. Regulla et al. describe implanting a metallic stent which has not been made radioactive, to maintain a lumen of a carotid artery open to allow adequate flow of blood therethrough. Gayer et al. describe determining extents of high attenuation objects and reducing artifacts that the high attenuation objects cause in an image without completely removing the high attenuation objects from the image. Walters describes taking two sets of measurements, one at a high kilovolts peak (KVP) at a specified dose level, and another at a low KVP and at a specified corresponding dose level. Accordingly, none of Arfelli, Urchuk et al., Vaillant et al., Regulla et al., Gayer et al., and Walters, considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities as recited in Claim 1. For the reasons set forth above, Claim 1 is submitted to be patentable over Arfelli and Urchuk et al., and further in view of Vaillant et al., Regulla et al., Gayer et al., and Walters.

When the recitations of Claim 13 are considered in combination with the recitations of Claim 1, Applicants submit that dependent Claim 13 likewise is patentable over Arfelli and Urchuk et al., and further in view of Vaillant et al., Regulla et al., Gayer et al., and Walters.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 13 over Arfelli and Urchuk et al., and further in view of Vaillant et al., Regulla et al., Gayer et al., and Walters.

The rejection of Claim 14 under 35 U.S.C. § 103(a) as being unpatentable over Arfelli in view of Urchuk et al. and Vinegar et al. is respectfully traversed.

Arfelli, Urchuk et al., and Vinegar et al. are described above.

Claim 14 recites a method for detecting components of plaque comprising "generating information regarding projection data of phantoms by using a multi-energy computed tomography (MECT) system; generating a look-up table by using one of the phantoms; obtaining the components of the plaque from the information; and enabling visualization of restenosis within one of a metal stent and a metal valve by repeating said obtaining the components of plaque after scanning a patient having the one of the metal stent and the metal valve."

None of Arfelli, Urchuk et al., and Vinegar et al., considered alone or in combination, describe or suggest a method for detecting components of plaque as recited in Claim 14. Specifically, none of Arfelli, Urchuk et al., and Vinegar et al., considered alone or in combination, describe or suggest enabling visualization of restenosis within one of a metal stent and a metal valve by repeating the obtaining the components of plaque after scanning a patient having the one of the metal stent and the metal valve. Rather, Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Vinegar et al. describe scanning a plurality of calibration materials which have a plurality of different known atomic numbers and densities with a computerized axial tomographic scanner (CAT) at first and second energies to determine attenuation coefficients for the plurality of calibration materials at the energies. Vinegar et al. further describe determining energy-dependent coefficients at the first and second energies from the attenuation coefficients for the plurality of calibration materials at the first and second energies. Vinegar et al. also describe scanning an unknown material with the CAT at the first and second energies to determine the attenuation coefficients at a plurality of points in a cross section of the unknown material at the energies. Vinegar et al. describe using the determined energy-dependent coefficients and the determined attenuation coefficients for the unknown material at the first and second energies to determine an atomic number image for the unknown material. Accordingly, none of Arfelli, Urchuk et al., and Vinegar et al., considered alone or in combination, describe or suggest enabling visualization of restenosis within one of a metal stent and a metal valve by repeating the obtaining the components of plaque after

scanning a patient as recited in Claim 14. For the reasons set forth above, Claim 14 is submitted to be patentable over Arfelli in view of Urchuk et al. and Vinegar et al.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 14 over Arfelli in view of Urchuk et al. and Vinegar et al.

The rejection of Claim 15 under 35 U.S.C. § 103(a) as being unpatentable over Schanen (U.S. Patent 5,218,533) in view of Arfelli and Urchuk et al. is respectfully traversed.

Arfelli and Urchuk et al. are described above.

Schanen describes a CT system. The CT system includes a CT gantry (16), that includes an x-ray source (10) oriented to project a fan beam of x-rays (24) from a focal spot (11) through an imaged object (12) to a detector array (18) (column 4, lines 31-36).

Claim 15 recites a multi-energy computed tomography (MECT) system comprising "at least one radiation source configured to transmit x-rays that intersect an object; at least one detector configured to detect the x-rays; a controller coupled to the detector; and a computer configured to: instruct the MECT system to detect components of plaque; generate a look-up table by using at least one phantom; repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent to accentuate a visualization of the plaque."

None of Schanen, Arfelli, and Urchuk et al., considered alone or in combination, describe or suggest a multi-energy computed tomography system as recited in Claim 15. Specifically, none of Schanen, Arfelli, and Urchuk et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent to accentuate a visualization of the plaque. Rather, Schanen describes a CT system that includes a CT gantry. The CT gantry includes an x-ray source oriented to project a fan beam of x-rays from a focal spot through an imaged object to a detector array. Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error

estimates. Accordingly, none of Schanen, Arfelli, and Urchuk et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent as recited in Claim 15. For the reasons set forth above, Claim 15 is submitted to be patentable over Schanen in view of Arfelli and Urchuk et al.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 15 over Schanen in view of Arfelli and Urchuk et al. be withdrawn.

The rejection of Claim 19 under 35 U.S.C. § 103(a) as being unpatentable over Schanen, Arfelli, Urchuk et al., and further in view of Walters and Aradate et al. (U.S. Patent Application Publication 2002/0131544) is respectfully traversed.

Schanen, Arfelli, Urchuk et al., and Walters are described above.

Aradate et al. describe at least one computer-readable medium or memory for storing data structures, tables, records, or other data (paragraph 65). Examples of the computer-readable media are compact discs, hard disks, floppy disks, tape, magneto-optical disks, PROMs (EPROM, EEPROM, Flash EPROM), DRAM, SRAM, and SDRAM (paragraph 65).

Claim 19 depends directly from independent Claim 15. None of Schanen, Arfelli, Urchuk et al., Walters, and Aradate et al., considered alone or in combination, describe or suggest a multi-energy computed tomography system as recited in Claim 15. Specifically, none of Schanen, Arfelli, Urchuk et al., Walters, and Aradate et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent to accentuate a visualization of the plaque. Rather, Schanen describes a CT system that includes a CT gantry. The CT gantry includes an x-ray source oriented to project a fan beam of x-rays from a focal spot through an imaged object to a detector array. Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Walters describes taking two sets of measurements, one at a

high kilovolts peak (KVP) at a specified dose level, and another at a low KVP and at a specified corresponding dose level. Aradate et al. describe at least one computer-readable medium or memory for storing data structures, tables, records, or other data. Accordingly, none of Schanen, Arfelli, Urchuk et al., Walters, and Aradate et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent as recited in Claim 15. For the reasons set forth above, Claim 15 is submitted to be patentable over Schanen, Arfelli, Urchuk et al., and further in view of Walters and Aradate et al.

When the recitations of Claim 19 are considered in combination with the recitations of Claim 15, Applicants submit that dependent Claim 19 likewise is patentable over Schanen, Arfelli, Urchuk et al., and further in view of Walters and Aradate et al.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 19 over Schanen, Arfelli, Urchuk et al., and further in view of Walters and Aradate et al. be withdrawn.

The rejection of Claim 20 under 35 U.S.C. § 103(a) as being unpatentable over Schanen, Arfelli, Urchuk et al., and further in view of Teirstein et al., Walters and Aradate et al. is respectfully traversed.

Schanen, Arfelli, Urchuk et al., Teirstein et al., Walters, and Aradate et al. are described above.

Claim 20 depends directly from independent Claim 15. None of Schanen, Arfelli, Urchuk et al., Teirstein et al., Walters, and Aradate et al., considered alone or in combination, describe or suggest a multi-energy computed tomography system as recited in Claim 15. Specifically, none of Schanen, Arfelli, Urchuk et al., Teirstein et al., Walters, and Aradate et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent to accentuate a visualization of the plaque. Rather, Schanen describes a CT system that includes a CT gantry. The CT gantry includes an x-ray source oriented to project a fan beam of x-rays from a focal spot through an imaged object to a detector array. Arfelli describes performing multiple energy computed tomography and

applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Teirstein et al. describe detecting a presence of detectable lipid-avid agent attached to a lipid accumulation in a wall of an artery. Walters describes taking two sets of measurements, one at a high kilovolts peak (KVP) at a specified dose level, and another at a low KVP and at a specified corresponding dose level. Aradate et al. describe at least one computer-readable medium or memory for storing data structures, tables, records, or other data. Accordingly, none of Schanen, Arfelli, Urchuk et al., Teirstein et al., Walters, and Aradate et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent as recited in Claim 15. For the reasons set forth above, Claim 15 is submitted to be patentable over Schanen, Arfelli, Urchuk et al., and further in view of Teirstein et al., Walters and Aradate et al.

When the recitations of Claim 20 are considered in combination with the recitations of Claim 15, Applicants submit that dependent Claim 20 likewise is patentable over Schanen, Arfelli, Urchuk et al., and further in view of Teirstein et al., Walters and Aradate et al.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 20 over Schanen, Arfelli, Urchuk et al., and further in view of Teirstein et al., Walters and Aradate et al. be withdrawn.

The rejection of Claim 21 under 35 U.S.C. § 103(a) as being unpatentable over Schanen, Arfelli, Urchuk et al., and further in view of Falotico et al., Walters, and Aradate et al. is respectfully traversed.

Schanen, Arfelli, Urchuk et al., Falotico et al., Walters, and Aradate et al. are described above.

Claim 21 depends directly from independent Claim 15. None of Schanen, Arfelli, Urchuk et al., Falotico et al., Walters, and Aradate et al., considered alone or in combination, describe or suggest a multi-energy computed tomography system as recited in Claim 15.

Specifically, none of Schanen, Arfelli, Urchuk et al., Falotico et al., Walters, and Aradate et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent to accentuate a visualization of the plaque. Rather, Schanen describes a CT system that includes a CT gantry. The CT gantry includes an x-ray source oriented to project a fan beam of x-rays from a focal spot through an imaged object to a detector array. Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Falotico et al. describe identifying a location of vulnerable plaques in a plurality of coronary arteries by using contrast agents. Walters describes taking two sets of measurements, one at a high kilovolts peak (KVP) at a specified dose level, and another at a low KVP and at a specified corresponding dose level. Aradate et al. describe at least one computer-readable medium or memory for storing data structures, tables, records, or other data. Accordingly, none of Schanen, Arfelli, Urchuk et al., Falotico et al., Walters, and Aradate et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent as recited in Claim 15. For the reasons set forth above, Claim 15 is submitted to be patentable over Schanen, Arfelli, Urchuk et al., and further in view of Falotico et al., Walters, and Aradate et al.

When the recitations of Claim 21 are considered in combination with the recitations of Claim 15, Applicants submit that dependent Claim 21 likewise is patentable over Schanen, Arfelli, Urchuk et al., and further in view of Falotico et al., Walters, and Aradate et al.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 21 over Schanen, Arfelli, Urchuk et al., and further in view of Falotico et al., Walters, and Aradate et al. be withdrawn.

The rejection of Claim 22 under 35 U.S.C. § 103(a) as being unpatentable over Schanen, Arfelli, and Urchuk et al., and further in view of Arnold is respectfully traversed.

Claim 22 has been canceled.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 22 over Schanen, Arfelli, Urchuk et al., and further in view of Arnold.

The rejection of Claim 23 under 35 U.S.C. § 103(a) as being unpatentable over Schanen, Arfelli, Urchuk et al., and Arnold, and further in view of Kaufman et al. is respectfully traversed.

Schanen, Arfelli, Urchuk et al., Arnold, and Kaufman et al. are described above.

Claim 23 depends indirectly from independent Claim 15. None of Schanen, Arfelli, Urchuk et al., Arnold, and Kaufman et al., considered alone or in combination, describe or suggest a multi-energy computed tomography system as recited in Claim 15. Specifically, none of Schanen, Arfelli, Urchuk et al., Arnold, and Kaufman et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent to accentuate a visualization of the plaque. Rather, Schanen describes a CT system that includes a CT gantry. The CT gantry includes an x-ray source oriented to project a fan beam of x-rays from a focal spot through an imaged object to a detector array. Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Arnold describes utilizing an improved calibration phantom formed of a material which simulates properties of human tissue and contains calcium in a stable configuration. Kaufman et al. describe indicating total plaque burden by quantifying coronary calcium burden. Accordingly, none of Schanen, Arfelli, Urchuk et al., Arnold, and Kaufman et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent as recited in Claim 15. For the reasons set forth above, Claim 15 is submitted to be patentable over Schanen, Arfelli, Urchuk et al. and Arnold, and further in view of Kaufman et al..

When the recitations of Claim 23 are considered in combination with the recitations of Claim 15, Applicants submit that dependent Claim 23 likewise is patentable over Schanen, Arfelli, Urchuk et al. and Arnold, and further in view of Kaufman et al.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 23 over Schanen, Arfelli, Urchuk et al. and Arnold, and further in view of Kaufman et al. be withdrawn.

The rejection of Claim 24 under 35 U.S.C. § 103(a) as being unpatentable over Schanen, Arfelli, Urchuk et al., and further in view of Charles, Jr. et al., Fox et al. and Aradate et al. is respectfully traversed.

Schanen, Arfelli, Urchuk et al., Charles, Jr. et al., Fox et al. and Aradate et al. are described above..

Claim 24 depends directly from independent Claim 15. None of Schanen, Arfelli, Urchuk et al., Charles, Jr. et al., Fox et al. and Aradate et al., considered alone or in combination, describe or suggest a multi-energy computed tomography system as recited in Claim 15. Specifically, none of Schanen, Arfelli, Urchuk et al., Charles, Jr. et al., Fox et al. and Aradate et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent to accentuate a visualization of the plaque. Rather, Schanen describes a CT system that includes a CT gantry. The CT gantry includes an x-ray source oriented to project a fan beam of x-rays from a focal spot through an imaged object to a detector array. Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Charles, Jr. et al. describe using a proportionality relationship to compute a tissue density based on equivalent thicknesses of a plurality of calibration materials. Fox et al. describe nutating a three-dimensional image with a nutation angle to display the three dimensional image from varying points of view. Aradate et al. describe at least one computer-readable medium or memory for storing data structures, tables, records, or other data. Accordingly, none of Schanen, Arfelli

Urchuk et al., Charles, Jr. et al., Fox et al. and Aradate et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent as recited in Claim 15. For the reasons set forth above, Claim 15 is submitted to be patentable over Schanen, Arfelli, Urchuk et al., and further in view of Charles, Jr. et al., Fox et al., and Aradate et al.

When the recitations of Claim 24 are considered in combination with the recitations of Claim 15, Applicants submit that dependent Claim 24 likewise is patentable over Schanen, Arfelli, Urchuk et al., and further in view of Charles, Jr. et al., Fox et al., and Aradate et al.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 24 over Schanen, Arfelli, Urchuk et al., and further in view of Charles, Jr. et al., Fox et al., and Aradate et al. be withdrawn.

The rejection of Claim 25 under 35 U.S.C. § 103(a) as being unpatentable over Schanen, Arfelli, Urchuk et al., and further in view of Vaillant et al., Regulla et al., Gayer et al., and Walters is respectfully traversed.

Schanen, Arfelli, Urchuk et al., Vaillant et al., Regulla et al., Gayer et al., and Walters are described above.

Claim 25 depends directly from independent Claim 15. None of Schanen, Arfelli, Urchuk et al., Vaillant et al., Regulla et al., Gayer et al., and Walters, considered alone or in combination, describe or suggest a multi-energy computed tomography system as recited in Claim 15. Specifically, none of Schanen, Arfelli, Urchuk et al., Vaillant et al., Regulla et al., Gayer et al., and Walters, considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent to accentuate a visualization of the plaque. Rather, Schanen describes a CT system that includes a CT gantry. The CT gantry includes an x-ray source oriented to project a fan beam of x-rays from a focal spot through an imaged object to a detector array. Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. describe estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed

with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates. Vaillant et al. describe reconstructing a three-dimensional image of an element of interest like, for example, a vascular stent inserted in an organ such as a vessel. Regulla et al. describe implanting a metallic stent which has not been made radioactive, to maintain a lumen of a carotid artery open to allow adequate flow of blood therethrough. Gayer et al. describe determining extents of high attenuation objects and reducing artifacts that the high attenuation objects cause in an image without completely removing the high attenuation objects from the image. Walters describes taking two sets of measurements, one at a high kilovolts peak (KVP) at a specified dose level, and another at a low KVP and at a specified corresponding dose level. Accordingly, none of Schanen, Arfelli, Urchuk et al., Vaillant et al., Regulla et al., Gayer et al., and Walters, considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent as recited in Claim 15. For the reasons set forth above, Claim 15 is submitted to be patentable over Schanen, Arfelli, Urchuk et al., and further in view of Vaillant et al., Regulla et al., Gayer et al., and Walters.

When the recitations of Claim 25 are considered in combination with the recitations of Claim 15, Applicants submit that dependent Claim 25 likewise is patentable over Schanen, Arfelli, Urchuk et al., and further in view of Vaillant et al., Regulla et al., Gayer et al., and Walters.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 25 over Schanen, Arfelli, Urchuk et al., and further in view of Vaillant et al., Regulla et al., Gayer et al., and Walters be withdrawn.

The rejection of Claims 26 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Arfelli in view of Zmora (U.S. Patent 6,028,909) and Ito et al. (U.S. Patent 5,122,664) is respectfully traversed.

Arfelli is described above.

Zmora describes a computer-based system and a method for correction of artifacts in computed tomography images (column 8, lines 24-25). The method could be programmed in a computer initially, or added later in an upgraded software package (column 8, lines 25-27).

Ito et al. describe a method in which a subtraction image S thus displayed is composed of a pattern S1 of a bone of an object (1) and a pattern S5 of a phantom 5 (column 13, lines 17-19). Therefore, the pattern S1 of the bone of the object and the pattern S5 of the phantom can be observed simultaneously (column 13, lines 19-21). One of a plurality of step-like sections in the pattern S5 of the phantom is found, which has an image density equal or close to the image density of a specific part of the pattern S1 of the bone, which part is to be analyzed for a determination of an amount of bone calcium (column 13, lines 21-26). Thereafter, the amount of bone calcium can be determined which corresponds to the image density (column 13, lines 26-28).

Claim 26 recites a computer readable medium encoded with a program configured to "instruct a computer to detect components of plaque within an object that is scanned using a multi-energy tomography (MECT) system, the program further configured to instruct the computer to generate, by using at least one phantom, a look-up table that maps different densities of a selected basis material of the phantom to projection data for different energy spectra, and to repeat the detection of the components of the plaque after instructing a user to administer a contrast agent to accentuate a visualization of the plaque."

None of Arfelli, Zmora, and Ito et al., considered alone or in combination, describe or suggest a computer readable medium as recited in Claim 26. Specifically, none of Arfelli, Zmora, and Ito et al., considered alone or in combination, describe or suggest a program further configured to instruct the computer to repeat the detection of the components of the plaque after instructing a user to administer a contrast agent to accentuate a visualization of the plaque. Rather, Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Zmora describes correcting artifacts in computed tomography images. Ito et al. describe finding one of a plurality of step-like sections in a pattern of a phantom, which has an image density equal or close to an image density of a specific part of a pattern of a bone. Ito et al. further describe determining an amount of bone calcium corresponding to the image density. Accordingly, none of Arfelli, Zmora, and Ito et al., considered alone or in combination, describe or suggest a program further configured to instruct the computer to repeat the detection of the components of the plaque after instructing a user to administer a contrast agent to accentuate a visualization of the plaque as recited in

Claim 26. For the reasons set forth above, Claim 26 is submitted to be patentable over Arfelli in view of Zmora and Ito et al..

Claim 27 recites a computer encoded with "a program configured to instruct an MECT system to detect components of plaque within an object that is scanned using the MECT system, the program further configured to instruct the computer to generate, by using at least one phantom, a look-up table that maps different densities of a selected basis material of the phantom to projection data for different energy spectra, and to quantify the components of the plaque by determining a weighted sum of densities, greater than a specific amount, of pixels of an image of an organ including the plaque."

None of Arfelli, Zmora, and Ito et al., considered alone or in combination, describe or suggest a computer as recited in Claim 27. Specifically, none of Arfelli, Zmora, and Ito et al., considered alone or in combination, describe or suggest the program further configured to quantify the components of the plaque by determining a weighted sum of densities, greater than a specific amount, of pixels of an image of an organ including the plaque. Rather, Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Zmora describes correcting artifacts in computed tomography images. Ito et al. describe finding one of a plurality of step-like sections in a pattern of a phantom, which has an image density equal or close to an image density of a specific part of a pattern of a bone. Ito et al. further describe determining an amount of bone calcium corresponding to the image density. Accordingly, none of Arfelli, Zmora, and Ito et al., considered alone or in combination, describe or suggest to quantify the components of the plaque by determining a weighted sum of densities, greater than a specific amount, of pixels of an image of an organ as recited in Claim 27. For the reasons set forth above, Claim 27 is submitted to be patentable over Arfelli in view of Zmora and Ito et al..

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claims 26 and 27 over Arfelli in view of Zmora and Ito et al. be withdrawn.

The rejection of Claim 1-4 under 35 U.S.C. § 103(a) as being unpatentable over Arfelli in view of Vinegar et al., Lazos et al. ("A Software Data Generator for Radiograph Imaging Investigations"), and Adriaansz (U.S. Patent 6,574,302) is respectfully traversed.

Arfelli and Vinegar et al. are described above.

Lazos et al. describe a method for developing and implementing an integrated software application used to create electronic phantoms, which can be subsequently subjected to a simulated X-ray imaging procedure to produce radiographic projection images (page 76, Introduction). Each of the images are composed on calculated intensity pixel values of transmitted radiation fluence reaching a detector (page 76, Introduction).

Adriaansz describes a method in which a value of a bone mineral density factor to be used can be looked up in a look-up table (column 4, lines 50-53). When the bone mineral density factor has been determined a priori, the values of this factor can be stored in a look-up table that is stored in a memory of a computer (column 4, lines 53-56).

Claim 1 is recited above. None of Arfelli, Vinegar et al., Lazos et al., and Adriaansz, considered alone or in combination, describe or suggest a method as recited in Claim 1. Specifically, none of Arfelli, Vinegar et al., Lazos et al., and Adriaansz, considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities of pixels of an image of an organ including the plaque. Rather, Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Vinegar et al. describe scanning a plurality of calibration materials which have a plurality of different known atomic numbers and densities with a computerized axial tomographic scanner (CAT) at first and second energies to determine attenuation coefficients for the plurality of calibration materials at the energies. Vinegar et al. further describe determining energy-dependent coefficients at the first and second energies from the attenuation coefficients for the plurality of calibration materials at the first and second energies. Vinegar et al. also describe scanning an unknown material with the CAT at the first and second energies to determine the attenuation coefficients at a plurality of points in a cross section of the unknown material at the energies. Vinegar et al. describe using the determined energy-dependent coefficients and the determined attenuation coefficients for the unknown material at the first and second energies to determine an atomic number image for the unknown material. Lazos et al. describe developing and implementing an integrated software application used to create electronic phantoms, which can be subsequently subjected to a simulated X-ray imaging procedure to produce radiographic projection images. Adriaansz

describes viewing a value of a bone mineral density factor in a look-up table. Accordingly, none of Arfelli, Vinegar et al., Lazos et al., and Adriaansz, considered alone or in combination, describe or suggest quantifying the components of the plaque by determining a weighted sum of densities as recited in Claim 1. For the reasons set forth above, Claim 1 is submitted to be patentable over Arfelli, and further in view of Vinegar et al., Lazos et al., and Adriaansz.

Claims 2-4 depend, directly or indirectly, from independent Claim 1. When the recitations of Claims 2-4 are considered in combination with the recitations of Claim 1, Applicants submit that dependent Claims 2-4 likewise are patentable over Arfelli, and further in view of Vinegar et al., Lazos et al., and Adriaansz.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claims 1-4 over Arfelli, and further in view of Vinegar et al., Lazos et al., and Adriaansz be withdrawn.

The rejection of Claims 15-17 under 35 U.S.C. § 103(a) as being unpatentable over Schanen in view of Arfelli, Vinegar et al., Lazos et al., and Adriaansz is respectfully traversed.

Schanen, Arfelli, Vinegar et al., Lazos et al., and Adriaansz are described above.

Claim 15 is recited above.

None of Schanen, Arfelli, Vinegar et al., Lazos et al., and Adriaansz, considered alone or in combination, describe or suggest a multi-energy computed tomography system as recited in Claim 15. Specifically, none of Schanen, Arfelli, Vinegar et al., Lazos et al., and Adriaansz, considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent to accentuate a visualization of the plaque. Rather, Schanen describes a CT system that includes a CT gantry. The CT gantry includes an x-ray source oriented to project a fan beam of x-rays from a focal spot through an imaged object to a detector array. Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Vinegar et al. describe using the determined energy-dependent coefficients and the determined attenuation coefficients for the unknown material

at the first and second energies to determine an atomic number image for the unknown material. Lazos et al. describe developing and implementing an integrated software application used to create electronic phantoms, which can be subsequently subjected to a simulated X-ray imaging procedure to produce radiographic projection images. Adriaansz describes viewing a value of a bone mineral density factor in a look-up table. Accordingly, none of Schanen, Arfelli, Vinegar et al., Lazos et al., and Adriaansz, considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent as recited in Claim 15. For the reasons set forth above, Claim 15 is submitted to be patentable over Schanen in view of Arfelli, Vinegar et al., Lazos et al., and Adriaansz.

When the recitations of Claims 16 and 17 are considered in combination with the recitations of Claim 15, Applicants submit that dependent Claims 16 and 17 likewise are patentable over Schanen in view of Arfelli, Vinegar et al., Lazos et al., and Adriaansz.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claims 15-17 over Schanen in view of Arfelli, Vinegar et al., Lazos et al., and Adriaansz be withdrawn.

The rejection of Claim 18 under 35 U.S.C. § 103(a) as being unpatentable over Schanen in view of Arfelli, Vinegar et al., Lazos et al., and Adriaansz, and further in view of Aradate et al. is respectfully traversed.

Schanen, Arfelli, Vinegar et al., Lazos et al., Adriaansz, and Aradate et al. are described above.

Claim 18 depends indirectly from independent Claim 15. None of Schanen, Arfelli, Vinegar et al., Lazos et al., Adriaansz, and Aradate et al., considered alone or in combination, describe or suggest a multi-energy computed tomography system as recited in Claim 15. Specifically, none of Schanen, Arfelli, Vinegar et al., Lazos et al., Adriaansz, and Aradate et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent to accentuate a visualization of the plaque. Rather, Schanen describes a CT system that includes a CT gantry. The CT gantry includes an x-ray source oriented to project a fan beam of x-rays from a focal spot through an imaged object to

a detector array. Arfelli describes performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Vinegar et al. further describe determining energy-dependent coefficients at the first and second energies from the attenuation coefficients for the plurality of calibration materials at the first and second energies. Vinegar et al. also describe scanning an unknown material with the CAT at the first and second energies to determine the attenuation coefficients at a plurality of points in a cross section of the unknown material at the energies. Vinegar et al. describe using the determined energy-dependent coefficients and the determined attenuation coefficients for the unknown material at the first and second energies to determine an atomic number image for the unknown material. Lazos et al. describe developing and implementing an integrated software application used to create electronic phantoms, which can be subsequently subjected to a simulated X-ray imaging procedure to produce radiographic projection images. Adriaansz describes viewing a value of a bone mineral density factor in a look-up table. Aradate et al. describe at least one computer-readable medium or memory for storing data structures, tables, records, or other data. Accordingly, none of Schanen, Arfelli, Vinegar et al., Lazos et al., Adriaansz, and Aradate et al., considered alone or in combination, describe or suggest a computer configured to repeat the detection of the components of the plaque after instructing a user to administer a temperature-sensitive contrast agent as recited in Claim 15. For the reasons set forth above, Claim 15 is submitted to be patentable over Schanen in view of Arfelli, Vinegar et al., Lazos et al., and Adriaansz, and further in view of Aradate et al.

When the recitations of Claim 18 are considered in combination with the recitations of Claim 15, Applicants submit that dependent Claim 18 likewise is patentable over Schanen in view of Schanen in view of Arfelli, Vinegar et al., Lazos et al., and Adriaansz, and further in view of Aradate et al.

For the reasons set forth above, Applicants respectfully request that the Section 103 rejection of Claim 18 over Schanen in view of Arfelli, Vinegar et al., Lazos et al., and Adriaansz, and further in view of Aradate et al. be withdrawn.

Moreover, Applicants respectfully submit that the Section 103 rejections of Claims 1-27 are not proper rejections. As is well established, obviousness cannot be established by combining the teachings of the cited art to produce the claimed invention, absent some

teaching, suggestion, or incentive supporting the combination. None of Urchuk et al., Arfelli, Vinegar et al., Lazos et al., Adriaansz, Tsutsui et al., Walters, Teirstein et al., Falotico et al., Arnold, Kaufman et al., Charles, Jr. et al., Fox et al., Ito et al., Vaillant et al., Regulla et al., Gayer et al., Schanen, Aradate et al., and Zmora, considered alone or in combination, describe or suggest the claimed combination. Furthermore, in contrast to the assertion within the Office Action, Applicants respectfully submit that it would not be obvious to one skilled in the art to combine Urchuk et al. with Arfelli, Vinegar et al., Lazos et al., Adriaansz, Tsutsui et al., Walters, Teirstein et al., Falotico et al., Arnold, Kaufman et al., Charles, Jr. et al., Fox et al., Ito et al., Vaillant et al., Regulla et al., Gayer et al., Schanen, Aradate et al., or Zmora because there is no motivation to combine the references suggested in the cited art itself.

As the Federal Circuit has recognized, obviousness is not established merely by combining references having different individual elements of pending claims. Ex parte Levengood, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). MPEP 2143.01. Rather, there must be some suggestion, outside of Applicants' disclosure, in the prior art to combine such references, and a reasonable expectation of success must be both found in the prior art, and not based on Applicants' disclosure. In re Vaeck, 20 U.S.P.Q.2d 1436 (Fed. Cir. 1991). In the present case, neither a suggestion or motivation to combine the prior art disclosures, nor any reasonable expectation of success has been shown.

Furthermore, it is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the cited art so that the claimed invention is rendered obvious. Specifically, one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the art to deprecate the claimed invention. Further, it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. The present Section 103 rejections are based on a combination of teachings selected from multiple patents in an attempt to arrive at the claimed invention. Specifically, Arfelli teaches performing multiple energy computed tomography and applying dual-photon imaging in the study of tissue characterization as carotid artery atherosclerotic plaque composition. Urchuk et al. teach estimating a set of detector-dependent gain errors by high-pass filtering attenuation measurements performed

with a stationary gantry over varying thicknesses of a calibration phantom and generating an array of polynomial-based look-up tables from the error estimates.

Moreover, Vinegar et al. teach scanning a plurality of calibration materials which have a plurality of different known atomic numbers and densities with a computerized axial tomographic scanner (CAT) at first and second energies to determine attenuation coefficients for the plurality of calibration materials at the energies. Vinegar et al. further teach determining energy-dependent coefficients at the first and second energies from the attenuation coefficients for the plurality of calibration materials at the first and second energies. Vinegar et al. also teach scanning an unknown material with the CAT at the first and second energies to determine the attenuation coefficients at a plurality of points in a cross section of the unknown material at the energies. Vinegar et al. teach using the determined energy-dependent coefficients and the determined attenuation coefficients for the unknown material at the first and second energies to determine an atomic number image for the unknown material. Tsutsui et al. teach separating X-ray photons transmitted through an object into two energy bands by using two discriminator comparators and conducting a pulse counting measurement by using a one-dimensional semiconductor radiation detector. Teirstein et al. teach detecting a presence of detectable lipid-avid agent attached to a lipid accumulation in a wall of an artery. Walters teaches taking two sets of measurements, one at a high kilovolts peak (KVP) at a specified dose level, and another at a low KVP and at a specified corresponding dose level. Vaillant et al. teach reconstructing a three-dimensional image of an element of interest like, for example, a vascular stent inserted in an organ such as a vessel. Regulla et al. teach implanting a metallic stent which has not been made radioactive, to maintain a lumen of a carotid artery open to allow adequate flow of blood therethrough. Gayer et al. teach determining extents of high attenuation objects and reducing artifacts that the high attenuation objects cause in an image without completely removing the high attenuation objects from the image. Lazos et al. teach developing and implementing an integrated software application used to create electronic phantoms, which can be subsequently subjected to a simulated X-ray imaging procedure to produce radiographic projection images. Adriaansz teaches viewing a value of a bone mineral density factor in a look-up table. Falotico et al. teach identifying a location of vulnerable plaques in a plurality of coronary arteries by using contrast agents. Arnold teaches utilizing an improved calibration phantom formed of a material which simulates properties of human tissue and contains calcium in a stable configuration.

Furthermore, Kaufman et al. teach indicating total plaque burden by quantifying coronary calcium burden. Charles, Jr. et al. teach using a proportionality relationship to compute a tissue density based on equivalent thicknesses of a plurality of calibration materials. Fox et al. describe nutating a three-dimensional image with a nutation angle to display the three dimensional image from varying points of view. Schanen teaches a CT system that includes a CT gantry. The CT gantry includes an x-ray source oriented to project a fan beam of x-rays from a focal spot through an imaged object to a detector array. Zmora teaches correcting artifacts in computed tomography images. Ito et al. teach finding one of a plurality of step-like sections in a pattern of a phantom, which has an image density equal or close to an image density of a specific part of a pattern of a bone Ito et al. further describe determining an amount of bone calcium corresponding to the image density. Aradate et al. teach at least one computer-readable medium or memory for storing data structures, tables, records, or other data. Since there is no teaching nor suggestion in the cited art for the combination, the Section 103 rejections appear to be based on a hindsight reconstruction in which isolated disclosures have been picked and chosen in an attempt to deprecate the present invention. Of course, such a combination is impermissible, and for this reason alone, Applicants request that the Section 103 rejections of Claims 1-27 be withdrawn.

For at least the reasons set forth above, Applicants respectfully request that the rejections of Claims 1-27 under 35 U.S.C. 103(a) be withdrawn.

In view of the foregoing amendments and remarks, all the claims now active in this application are believed to be in condition for allowance. Reconsideration and favorable action is respectfully solicited.

Respectfully Submitted,

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